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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,101	12/18/2000	Lixiao Wang	S63.2-9285	5268

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6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER
HOEY, ALISSA L

ART UNIT	PAPER NUMBER
3765	

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/740,101	WANG, LIXIAO	
	Examiner	Art Unit	
	Alissa L. Hoey	3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 4 is objected to because of the following informalities: in line 9, should "send" read "second"?. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in claim 4, which "second end portion" you are referring to, the balloon or the catheter?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 4, 6, 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischell et al. (US 6,221,043).

Fishcell et al. provides a stent delivery system comprising a catheter having a catheter shaft and a medical balloon mounted thereto. The medical balloon having a non-inflated state and being inflatable to an inflated state, a stent mounting region and a

stent disposed about at least a portion of the stent mounting region. The stent mounting region having a middle portion, a first end portion adjacent to the middle portion and a second end portion adjacent to the middle portion (figures 2 and 5). The middle portion having a diameter that is greater than the first and second end portion's diameters in the non-inflated state. The middle, first end and second end portions having the same diameters when in the inflated state. A first cone being adjacent to the first end portion and having a first waist engaged to a first portion of the catheter shaft and the first end diameter being greater than the first waist diameter. A second cone being adjacent to the second end portion and having a second waist engaged to a second portion of the catheter shaft and the second end diameter being greater than the second waist diameter (figure 2, identifiers 14 and 18). The stent having an unexpanded state and an expanded state with a center, first and second end (column 7, lines 45-63).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 3, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.

Fischell et al. provides a stent delivery system as described above in claim 1. However, Fishcell et al. fails to teach when the medical balloon expands the middle portion pushes against the stent before the first end portion and before the second end

portion. The balloon in the non-inflated state has a middle portion diameter between .1-.25mm greater than the first and second end portion diameters and the stent center is expanded before the fist and second stent end portion. The balloon being manufactured from polyesters, polyethylene terephtalate, polybutylene terephathalate, etc.

It would have been obvious to have provided the balloon manufactured from a variety of suitable polymer materials, including polyethylene terephtalate, polyesters, polyubutylene terephatahalate, etc., since all are polymers that are suitable for medical balloon devices and supported in Applicants specification (page 5, lines 6-14).

It would have been further obvious to have provided the balloon expanding the middle portion of the stent before the first end and second end portions, since the stent conforms to the shape of the balloon, and when the balloon is filled with air it would be obvious for the middle section with a larger diameter to expand relative to the side portions that have a smaller diameter creating an apex in the balloon at the middle portion with the stent conforming thereto.

7. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. in view of Penderson, Jr. et al. (US 6,280,412).

Fischell provides a stent delivery system as described above in claims 1 and 6. However, Fischell fails to teach the stent comprising retaining sleeves with a stent retaining portion and a catheter shaft engaging portion. The retaining sleeves being retracted off the stent end during expansion of the stent, releasing the stent from the retaining sleeves. Penderson, jr. et al. teaches a stent comprising retaining sleeves with a stent retaining portion and a catheter shaft engaging portion (figure 10, identifier 40

and 42). The retaining sleeves being retracted off the stent end during expansion of the stent, releasing the stent from the retaining sleeves (figure 10, identifiers 40 and 42).

It would have been obvious to have provided the stent delivery system of Fischell et al. with the retaining sleeves of Penderson, Jr., et al., since the retracting retaining sleeves allow the cones to expose the stent for expansion upon further inflation of the balloon.

8. Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penderson, Jr. et al. in view of Bagaoisan et al. (US 5,415,635).

Penderson, Jr. et al. provides a stent delivery system comprising a catheter having a catheter shaft and a medical balloon mounted thereto (column 1, lines 5-13). The medical balloon having a non-inflated state and being inflatable to an inflated state, a stent mounting region and a stent disposed about at least a portion of the stent mounting region (figures 10 and 11). The stent mounting region having a middle portion, a first end portion adjacent to the middle portion and a second end portion adjacent to the middle portion (figures 2 and 5). The middle, first end and second end portions having the same diameters when in the inflated state (figure 10). A first cone being adjacent to the first end portion and having a first waist engaged to a first portion of the catheter shaft and the first end diameter being greater than the first waist diameter (Figure 10, identifiers 32). A second cone being adjacent to the second end portion and having a second waist engaged to a second portion of the catheter shaft and the second end diameter being greater than the second waist diameter (figure 10, identifier 34). The stent having an unexpanded state and an expanded state with a center, first

and second end (figures 10 and 11, identifier 36). .Further, Penderson, jr. et al. teaches a stent comprising retaining sleeves with a stent retaining portion and a catheter shaft engaging portion (figure 10, identifier 40 and 42). The retaining sleeves being retracted off the stent end during expansion of the stent, releasing the stent from the retaining sleeves (figure 10, identifiers 40 and 42). However, Penderson, jr. et al. fails to teach the balloons middle portion having a diameter that is greater than the first and second end portions diameters in the non-inflated state. When the medical balloon expands the middle portion pushes against the stent before the first end portion and before the second end portion. The balloon in the non-inflated state has a middle portion diameter between .1-.25mm greater than the first and second end portion diameters and the stent center is expanded before the first and second stent end portions. The balloon being manufactured from polyesters, polyethylene terephtalate, polybutylene terephathalate, etc.. Further, Penderson, Jr. fails to teach the diameter of the middle portion of the balloon in the non-inflated state being less than the diameter of the first and second end portions of the balloon in the non-inflated state.

It would have been obvious to have provided the balloon manufactured from a variety of suitable polymer materials, including polyethylene terephtalate, polyesters, polyubutylene terephatahalate, etc., since it is well known that all these materials are used in making medical balloons.

It would have been obvious to have provided the stent delivery system of Penderson with the balloon having first and second end portions with greater diameters than the middle portion of Bagaosian et al., since the balloon having a middle portion

with a smaller diameter than the end portions provides a balloon in the non-inflated state capable of conforming better to a patient's clogged passageways.

It would have been further obvious to have provided the balloon of Bagaosian et al. expanding the first and second end portions of the stent before the middle portion, since the stent conforms to the shape of the balloon and when the balloon is filled with air it would be obvious for the first and second end portions with a larger diameter to expand relative to the middle portion having a smaller diameter creating two apexes in the balloon at the first and second end portions with the stent conforming thereto.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bagaosian et al., Adams et al., Freund et al., Durcan et al., Tower, Penderson, Jr. et al., Miller et al., Hamilton et al. and Crocker et al. are all cited to show closely related medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alissa L. Hoey whose telephone number is (703) 308-6094. The examiner can normally be reached on M-F (8:00-5:30)Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.

alh
August 22, 2002

JOHN J. CALVERT
SUPERVISORY PATENT EXAMINER
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